REMARKS

Claims 1-37, 39-46, and 51-56 are pending. Applicants have made minor amendments to Claims 1, 13, 25, 37, and 46. Support for these amendments can be found in the respective claims, themselves. The Applicants submit that these minor amendments and corrections herein are made without prejudice as to patentability, including the doctrine of equivalents, and that no new matter has been added.

Claims 1-37, 39-46, and 51-56 Are Not Obvious

The Examiner rejected Claims 1-37, 39-46, and 51-56 under the provisions of 35 U.S.C. § 103(a) as being unpatentable over "The Effects of Hospital Contracting for Physician Services on Hospital Performance" (hereinafter "Snail") allegedly published in the Spring of 2000, in view of U.S. Patent No. 6,000,828 (hereinafter "Leet"). Applicants respectfully traverse the rejection.

Snail and Leet Fail to Recognize the Problem or Source of the Problem

As an initial matter, neither Snail nor Leet recognize the specific source of the problem as identified, addressed and solved by embodiments of Applicants' claimed invention. As noted previously, the Supreme Court in the famous case of *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923), has long acknowledged that recognition of a problem not previously recognized by others is part of the invention. *See also* MPEP 2141.02III ("[A] patentable invention may lie in the discovery of the source of a problem...."). Applicants' recognition of the source of the problem and methodology or solution to address and solve the particular problem in this case relates to gathering data on physician cost control risk or behavior, identifying those physicians at a greater risk, and behavior modification of physicians to reduce or control costs or expenses associated with such risk. Applicants submit that the recognition of this problem and the elegant solution provided by Applicants' claimed invention is an indicator of nonobviousness of the invention.

In particular, for example, Claim 1 includes the solution of controlling costs by gathering information in a computer medium on ancillary pharmacy costs for each of a plurality of physicians in a healthcare practice, identifying at least one of the physicians that is at a greater risk of not getting reimbursements by prescribing medications that are detrimental to receiving

reimbursement, and modifying management behavior for those at risk of not receiving reimbursement. Also, for example, as in Claim 13 it can be applicable in an insurance network, and as in Claim 25 it can have a financial incentive to the insurance network and/or physicians. As such, Applicants clearly have provided an elegant methodology or solution to these problems. The specific recognition of the source of the problem and elegant methodology or solution are not found in the cited references--not alone or in combination.

Persons of ordinary skill in the art who endeavor to solve the problem recognized and claimed by Applicants would *not* seek out the cited patent documents, which both alone and in combination fail to recognize the problems solved by the Applicants' claimed methodology.

No Prima Facie Case of Obviousness

Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, at least three basic criteria must be met. There must be some suggestion or motivation, either in the prior art references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the reference or teachings. Also, there must be a reasonable expectation of success in modifying or combining references. Finally, the prior art references, as combined, must teach or suggest all the claim elements. The teaching, motivation, or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on Applicant's disclosure. *See King Instrument Corp. v. Otari Corp.*, 767 F2d 853 (Fed. Cir. 1985). *See In re Vaeck,* 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

No Motivation to Combine Snail and Leet

Applicants respectfully submit that the Examiner has failed to meet the first element of a *prima facie* case for obviousness. First, there is no explicit suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. The Examiner has the burden of showing, as such, and has not met it here. Nor is there anything implicit suggesting combining the references, as the combined teachings, knowledge of one of ordinary skill in the art, and nature of the problem to be solved, as a whole, would not suggest doing so to those of ordinary

skill in the art, as is required in MPEP 2143.01 and *In re Kotzab,* 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000).

Neither Snail nor Leet is directed to a system or method of managing a healthcare practice participating in an insurance network to enhance profitability of the healthcare practice with respect to a predetermined reimbursement amount for ancillary pharmacy or ancillary medical costs. In fact, Snail and Leet are different to the point of being non-analogous references. For example, Snail as a whole describes the effects of hospital contracting for physician services on hospital performance. Leet as a whole describes a methodology of improving drug effectiveness for a specific treatment for a specific populace by determining emerging patterns of microbial drug resistance in a community and altering patterns of antimicrobial prescribing to reduce, and thus, solves the problem of, microbial evolutionary pressures that produce resistant organisms. Embodiments of Applicants claimed invention as a whole describes methods of and systems for enhancing profitability of a healthcare practice with respect to ancillary medical and pharmacy costs. Additionally, both Snail and Leet apply only to hospitals or closed healthcare systems where the claimed embodiments of Applicants invention applies to outpatient care or open healthcare systems. This is an important distinction because closed healthcare systems have different procedures, authorization, management, and record-keeping requirements. Thus, the combined teachings, knowledge of one of ordinary skill in the art, and nature of the problem to be solved, as a whole (enhancing profitability of a healthcare practice participating in an insurance network regarding management of ancillary medical costs), do not suggest combining these disparate references, as the combination would not solve the Applicants' problem.

Second, even if the references somehow could be combined or modified, this still is not sufficient to establish a *prima facie* obviousness unless the references also suggest the desirability of the combination. *See* MPEP 2143.01. In the present case, there is no suggestion as to the desirability of the combination. One must keep in mind that Snail is a dissertation discussing the effects of "hospital contracting" for physician services on "hospital performance" rather than on solving healthcare practice profitability issues. *See* Snail, abstract, para. 1. Leet provides a tool that can be used to recommend drug treatments which are allowed to evolve in response to changing medical information, side effects encountered, and patterns of disease

resistance, to thereby recommended treatments; evaluate drug treatments to help improve drug treatments in the community in which the treatment is being provided; detect emerging patterns of microbial drug resistance in a community; and alter patterns of antimicrobial prescribing to reduce microbial evolutionary pressures that produce resistant organisms. *See* Leet, col. 3, lines 10-25.

Third, the Examiner's statements, alone, that it would have been obvious to incorporate a computer tangible medium into the system of Snail is insufficient to establish a *prima facie* case of obviousness, even assuming the combination would actually solve the problems (which it would not). Even assuming a motivation and an ability to combine the references, MPEP 2143.01III states the "fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the *desirability* of the combination." (Emphasis added). Neither of these disparate references suggest such desirability.

Clearly, there is no motivation or suggestion to combine such disparate teachings in these patent references to somehow (by improper hindsight) arrive at the claimed invention, and each of these alone, and in combination, fails to teach or suggest the claimed embodiments of the invention. Therefore, Applicants further respectfully submit that the claimed embodiments of the invention are novel, non-obvious, and defines over Snail and Leet.

No Reasonable Expectation of Success

As will be described in more detail below, even if the references could be combined, Leet does not disclose, teach, or suggest gathering data regarding physicians in a healthcare group in a tangible computer medium. Rather Leet gathers data regarding specific diseases and treatment in order to form an intelligent diagnostic tool which can provide *to* a physician a recommended treatment including comparative drug costs, predicted total number of unit doses, and projected total cost of administering each recommended treatment. *See* Leet, col. 3, line 41 to col. 4, line 41. This is not the same as gathering in a tangible computer medium from [(for)]...physicians in a healthcare practice...ancillary medical or pharmacy costs data, identifying certain physicians from the tangible computer medium..., or modifying management behavior of at least one...physician.... Without recognition of the source of the problems identified and addressed

by the inventors in the subject patent application, Snail and Leet simply could not know, and therefore could not describe, what to change in order to solve such problems. Therefore, the second element of a *prima facie* case of obviousness has not been satisfied, and for this reason as well, the claimed invention is not obvious and defines over the cited references.

Snail and Leet Do Not Teach or Suggest All the Claim Elements

Applicants submit that neither of these references (namely, Snail and Leet), alone or in combination, teach or suggest all of the elements of the claimed embodiments of the present invention. The Examiner references Appendix 2 of Snail for the premise that Snail, in general, teaches the identifying and the modifying steps of, for example, Claim 1, and Leet, col. 15, lines 11-28, for the premise that Leet teaches the gathering step. Applicants respectfully submit the Examiner is mistaken. Snail, like previously cited Freeman and Dang, describes "administrative" methods. Embodiments of the claimed invention instead teach cost "control." As noted previously, when addressing a change program, for instance, the process must address: (1) what to change, (2) what to change to, and (3) how to cause or affect the change. Snail, even when combined with Leet, fails to offer a change process or solution. In contrast, embodiments of the claimed invention offer a solution for measuring or controlling costs and cost-effectiveness of care.

More particularly, Snail discloses that statistical profiles can be used to gather data and compare individual physicians to other peer physicians. Snail, however, does not disclose, teach, or suggest that "incentive payments are...based on [ancillary medical] costs." Snail, page 161, lines 1-4, references a footnote which shows results of a physician compensation survey on physician group practices offering incentive-based payments. Applicants believe that the Examiner is using such information to somehow extract a teaching of controlling physician behavior through use of ancillary medical costs. The data provided, however, indicates that group practice incentive payments averaged 10% of total compensation. Of this, only 10% of the 10% was based on "service and overhead costs." In other words, there was only a 1% total impact. Further, the data provided that just over half of the Hospitals have incentive payments, which average 15% of total compensation, but there is no mention of "service and overhead costs" impact. Finally, Integrated Delivery Systems incentive payments average 5% of total

compensation, and again, there is no mention of "service and overhead costs" impact. There is clearly indicated only a miniscule impact of costs on incentives. *See* Snail, page 161, lines 15-30. As such, nothing in Snail discloses, teaches, or suggests that ancillary medical costs including pharmacy costs are or should be a driving incentive factor. Thus, contrary to the teachings of Applicant, even excessively high ancillary medical or pharmacy costs combined with some other factors important to Snail could result in a maximum or near maximum incentive payment, according to Snail. Therefore, Snail clearly does not teach or suggest that ancillary medical or pharmacy costs should be used to control physician behavior as featured in Independent Claims 1, 13, or 25.

Snail not only does not teach or suggest such features, in reading Snail, one could further conclude that Snail inherently teaches away from utilization of ancillary medical costs including pharmacy costs to control physician behavior. Applicants describe this as an inherent teaching because the author of the Snail dissertation explicitly stated that the available data provided in Appendix 2 "do[es] not permit hypothesis testing." *See* Snail, page 5, lines 1-3. Thus, Snail explicitly indicates that he did not have all the facts necessary to analyze governance mechanisms in physician practice organizations or the intention to test them, making Snail generally, and Appendix 2 specifically, a non-enabling disclosure. *See* MPEP 2121.02I (analogously stating with respect to compounds and compositions, "the mere naming of a compound in a reference, without more, cannot constitute a description of the compound.").

Nevertheless, the Examiner cites Snail, page 162-163, as indicating that, with respect to general utilization management, education is a method of modification of physician behavior. "Education," however, is only mentioned once in the context of stating that "utilization management incentives can be instilled by...the structure of physician group practices, which encourages ongoing peer review, education, and innovation through a nonadversarial relationship." Thus, the term "education" is a characteristic of the structure of physician group practices and not any sort of payment mechanism. *See* also page 163, Table A2.3 (listing utilization management mechanisms but not including education as a utilization management mechanism).

Further, regardless of whether or not Snail discloses education as a method of modifying physician behavior (or any other professional for that matter), Snail does not disclose, teach, or

suggest applying such education to ancillary medical or pharmacy costs to modify physician behavior with respect to such costs. Applicants were unable to identify any passage indicating such teaching or suggestion either within or outside the pages cited by the Examiner. Modifying physician behavior with respect to ancillary medical or pharmacy costs is an important feature correspondingly not disclosed, taught, or suggested by either Snail or Leet.

Further, as noted previously, even if there was motivation to combine Snail and Leet (which Applicants contend there is not), Leet does not "fill in the blanks." That is, Leet does not disclose, teach, or suggest gathering data regarding *physicians* in a healthcare group in a tangible computer medium. Rather Leet gathers data regarding specific diseases and treatment in order to form an intelligent diagnostic tool which can provide *to* a physician a recommended treatment including comparative drug costs, predicted total number of unit doses, and projected total cost of administering each recommended treatment, etc. *See* Leet, col. 3, line 41 to col 4, line 41.

Therefore, the third element of a *prima facie* case of obviousness has not been satisfied. Accordingly, in view of the lack of motivation to combine the disparities in the cited references, overall failure to recognize the source of the problem as recognized by Applicants, lack of a reasonable expectation of success in developing claimed embodiments of the Applicants invention even using Applicants specification as a roadmap to do so, and lack of teaching or suggestion of each element of each independent claim, Applicants respectfully submit that Claims 1, 13, and 25 are novel, nonobvious and patentable over the cited references. Note, independent system Claims 37 and 46 are also novel, nonobvious, and patentable over the cited references for the reasons provided above.

The dependent Claims 2-12, 14-24, and 26-36 (and Claims 39-45, and 51-56) have therefore also been shown to be allowable because their corresponding independent claims have been shown to be novel and non-obvious. Nevertheless, the dependent claims include independent novelty. For example, regarding Claims 2 and 14, neither Snail nor Leet disclose, teach, or suggest gathering information regarding the ancillary pharmacy (or medical) costs of each of the plurality of physicians in the healthcare practice participating in an insurance (or medical) network. Although Leet teaches gathering drug cost data from a drug inventory and cost database 28c, the data is not aggregated costs for the physician or the practice, as featured in the claims. Further, such data is presented as a unique formula to rank medications to treat a

given condition (see col. 23, lines 7-8), which does not have not have a resulting unit of measure, because it adds both a time component, i.e., "average times drug administered per day" and cost components (see col. 23, line 19).

Regarding Claims 3 and 15, neither Snail nor Leet nor the Examiner's official notice disclose, teach, or suggest analyzing the ancillary pharmacy (or medical) costs of each of a plurality of physicians in a healthcare practice, calculating an average ancillary pharmacy (or medical) costs per physician for the healthcare practice, or identifying the physicians that have ancillary pharmacy (or medical) costs that are a predetermined percentage greater than the average ancillary pharmacy (or medical) costs per physician for the healthcare practice. *See* Snail, page 156. The Examiner states that Snail discloses analyzing ancillary pharmacy costs. Snail, however, instead only states that "[p]hysician profiles are compared to practice guidelines for other physician practices to evaluate performance...essential to the negotiation and structuring of managed care contracts." *See* Snail, page 156, lines 6-7. These "physician profiles" are for "Selective Contracting" (page 155 Section Title) and not profiles in the management of ancillary pharmacy (or medical) costs, as featured in the claims. Snail defines "selective contracting" as "a constrained payment system in which buyers contract with a limited number of sellers based on their qualifications and prior performance, thereby establishing a competitive bidding process" (page 155, line 2-4). Snail defines "profiles" as a selective contracting tool that "compare[s] individual or collective physician practices to their peers along such dimensions as resource consumption (e.g. ancillary procedure usage), charges, and patient volumes and outcomes; some hospitals also track malpractice claims and third-party payment denials." *See* Snail, page 156, lines 1-4. Nowhere in that definition are any costs or, specifically, ancillary medical or pharmacy costs, mentioned as a measured component for selective contracting. Therefore, it is evident that the term "profiles" is used by Snail in a manner for contract management and not in a manner for ancillary cost management nor updating physicians of changes in their individual costs relative to their peers. Further, even if generally calculating averages and identifying entities is well-known in the art of statistical profile, as premised by the Examiner, application to physicians in a healthcare practice with respect to ancillary medical or pharmacy costs *is not*.

Regarding Claims 4 and 16, neither Snail nor Leet disclose, teach, or suggest selecting a physician having the highest ancillary pharmacy (or medical) costs within the healthcare practice, as featured in the claims. Although the Examiner cites Snail, page 156, Applicants were unable to find any teaching or suggestion directed to such feature(s).

Regarding Claims 5 and 17, neither Snail nor Leet disclose, teach, or suggest educating the at least one physician on the benefits of alternative ancillary medical procedures or prescription medications using research literature for comparing the alternative ancillary medical procedures or medications to the current ancillary medical procedures or the prescribed medications, respectively, and organizing continued medical education classes to educate each of the plurality of physicians in the healthcare practice on the benefits of the alternative ancillary medical procedures or prescription medications, as featured in the claims. Although the Leet algorithm arguably provides a physician a recommended drug treatment according to a ranked selection, col. 14, lines 26-30, the algorithm does not provide continued medical education classes to educate each of a plurality of physicians in a healthcare practice on the benefits of the alternative ancillary medical procedures or prescription medications.

Regarding Claims 6 and 18, neither Snail nor Leet disclose, teach, or suggest preparing a list of ancillary medical procedures or prescription medications, that at least one physician may prescribe or engage in, that enable a physician to receive the predetermined reimbursement amount for the ancillary medical or pharmacy costs, as featured in the claims. Although the Leet algorithm arguably provides a physician a recommended drug treatment according to a ranked selection, col. 14, lines 26-30, the ranking formula does not include a "predetermined reimbursement amount for ancillary pharmacy [or medical] costs" as part of its ranking criteria. *See* Leet, col. 23, lines 7-37.

Regarding Claims 7 and 19, neither Snail nor Leet disclose, teach, or suggest providing custom prescription medication or medical procedure forms that include the list of prescription medications or ancillary medical procedures, respectively, that at least one physician may prescribe or engage in that enable the at least one physician to receive the predetermined reimbursement amount for the ancillary pharmacy or medical procedure costs. Leet shows database information in a closed system database accessible using a diagnosis code (entered into a hospital record) organized into a record shown in Table III. *See* Leet, col. 10, lines 24-28 and

col. 18, lines 34-40. Even if this table were considered a custom prescription or medical procedure form, which Applicants contend it is not, none of the Table III elements include a predetermined reimbursement amount nor such indication of reimbursement related to some drugs but not others.

Regarding Claims 8, 20, and 24, neither Snail nor Leet disclose, teach, or suggest preparing a list of common ancillary medical procedures or prescription medications that are approved by each of the plurality of insurance networks so as to enable at least one physician to receive the predetermined reimbursement amount for the ancillary pharmacy or medical costs. That is, although Leet arguably provides a list of suggested medications and associated costs, Leet (and Snail) not only say nothing of having a relationship to multiple insurance networks, clearly neither indicates a list prescription medications or ancillary medical procedures common to such plurality of insurance networks, as is featured in the claims.

Regarding Claim 9, neither Snail nor Leet disclose, teach, or suggest analyzing a patient's prescription history to thereby avoid possible adverse prescription medication reactions as part of a behavior modification process, as featured in the claim.

Regarding Claims 10 and 21, neither Snail nor Leet disclose, teach, or suggest identifying at least one patient whose present prescription medications (or ancillary medical procedures) put the at least one physician at risk for not receiving the predetermined reimbursements for the ancillary pharmacy (or medical) costs, amending the at least one patient's present prescription medications (or ancillary medical procedures) to decrease the at least one physician's risk of not receiving the predetermined reimbursements for the ancillary pharmacy (or medical) costs, and discontinuing the at least one patient's present prescription medications (or ancillary medical procedures) that put the at least one physician at risk for not receiving the predetermined reimbursements for the ancillary pharmacy (or medical) costs. Although Leet suggests modifying the previously described protocol by eliminating drugs that are poorly tolerated by the community patient population or found to have an adequate clinical effect (col. 19, lines 30-34), this criteria does not include a physician's risk of not receiving a predetermined reimbursement for ancillary pharmacy (or medical) costs, as featured in the claims.

Regarding Claims 11 and 22, neither Snail, Leet nor the Examiner's official notice disclose, teach, or suggest a physician providing a combination of both a first letter informing the

pharmacy (or ancillary medical facility) that the at least one patient's present prescription medication (or ancillary medical procedures) is discontinued and the second letter informing the at least one patient that the patient's present prescription medication (or ancillary medical procedures) is discontinued, as featured in the claims.

Regarding Claims 12 and 23, neither Snail nor Leet disclose, teach, or suggest updating each of a plurality of physicians in a healthcare practice of any changes in the management of ancillary pharmacy or medical costs from the insurance network, respectively, as featured in the claims. First, as noted previously, neither Snail nor Leet teach or suggest procedures involving ancillary medical or pharmacy costs from an insurance network. Further, nowhere in the Snail definition of "profiles" are any costs or, specifically, ancillary pharmacy costs, mentioned as a measured component for its "selective contracting." Therefore, it is evident that "profiles" is used by Snail in a manner for contract management and not in a manner for ancillary cost management or updating physicians of changes in their individual costs relative to their peers.

Regarding Independent Claim 25, as described previously primarily with respect to Claim 1, neither Snail nor Leet, alone or in combination, disclose, teach, or suggest the gathering, identifying, or modifying management behavior steps. Further, neither Snail nor Leet, alone or in combination, disclose, teach, or suggest providing a financial incentive to both an insurance network *and* a plurality of physicians in the healthcare practice participating in an insurance network to modify the plurality of physicians' management behavior of ancillary medical costs that are not as profitable to the insurance network. As stated previously, neither Snail nor Leet teach behavior management through ancillary medical cost reimbursements. *See* Snail page 156 and 161. Further, neither Snail nor Leet are directed to a healthcare practice participating in an insurance network. Both are directed to implementation within a closed system, e.g., hospital environment.

Regarding Independent System Claims 37 and 46, neither Snail nor Leet, alone or in combination, disclose, teach, or suggest at least the following: a first database comprising ancillary medical procedures that are preferred by the insurance network; a second database comprising ancillary medical costs of each of the plurality of physicians participating in the insurance network; an analyzer for analyzing the data in the first and second database and comparing the ancillary medical procedures that are preferred by the insurance network with the

ancillary medical costs of the plurality of physicians participating in the insurance network to thereby identify ancillary medical costs of the physicians that are not preferred by the insurance network; and managing means responsive to the analyzer for managing the ancillary medical costs of the healthcare practice identified as not being preferred by the insurance network to thereby modify the ancillary medical costs of the physicians in the healthcare practice to be more profitable to the insurance network. Particularly, Applicants were unable to identify any passage in either Snail or Leet indicating a teaching or suggestion with respect to providing at least the following: an analyzer to compare ancillary medical procedures preferred by an insurance network with ancillary medical costs of physicians in a healthcare practice participating in the insurance network to identify those non-preferred ancillary medical costs being incurred, or managing those ancillary medical costs identified as not being preferred by an insurance network. These are important features correspondingly not disclosed, taught, or suggested by either Snail or Leet. As such, Claims 37 and 46 have been shown to be allowable and define over the cited references.

The dependent Claims 39-45, and 51-56 have also been shown to be allowable because their corresponding independent claims, Claims 37 and 46, respectively, have been shown to be novel and non-obvious. Nevertheless, the dependent claims include independent novelty. For example, neither Snail nor Leet, alone or in combination, disclose, teach, or suggest a calculating means for calculating an average ancillary medical cost per physician for the healthcare practice, etc., as featured in Claims 39 and 51; an educator as featured in Claims 40 and 52; custom medical procedure forms including ancillary medical procedures that are preferred by the insurance network, as featured in Claims 41 and 53; patient intervening means as featured in Claims 42 and 54; generating means for generating letters to both a medical facility and a patient providing notification of a change in ancillary medical procedures, as featured in Claims 43 and 55; and an updater for updating physicians in the healthcare practice of any changes in the management of ancillary medical costs, as featured in Claim 44 and 45.

In commenting upon the references and in order to facilitate a better understanding of the differences that are expressed in the claims, certain details of distinction between the references and the claimed invention have been mentioned, even though such differences do not appear in all of the claims. It is not intended by mentioning any such unclaimed distinctions to create any

implied limitations in the claims. Not all of the distinctions between the prior art and Applicants' claimed invention have been made by Applicants. For the foregoing reasons, Applicants reserve the right to submit additional evidence showing the distinctions between Applicants claimed invention to be nonobvious in view of the cited references.

The foregoing remarks are intended to assist the Examiner in re-examining the application and in the course of explanation may employ shortened or more specific or variant descriptions of some of the claim language. Such descriptions are not intended to limit the scope of the claims; the actual claim language should be considered in each case. Furthermore, the remarks are not to be considered to be exhaustive of the facets of the claimed invention that render it patentable, being only examples of certain advantageous features and differences that Applicants' attorney chooses to mention at this time.

CONCLUSION

In view of the above remarks, Applicants submit that the Application is in condition for allowance. As such, the issuance of a Notice of Allowance is respectfully requested.

Respectfully submitted,

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